

Baldwin Optical and Hearing Aid Co.  
310 E. Laurel Ave.  
Foley, AL 36535  
334-943-1758

To Honorable Donna Shalala  
Secretary of Health and Human Svcs  
Room 615 F  
200 Independence Ave., SW  
Washington, D.C. 20201

Dear Hon. Donna Shalala,

The Food and Drug Administration is in the process of proposing changes to the way hearing aids are sold that could put me out of business and impede access to hearing care services for millions of our nations' hearing impaired.

I am a Board Certified, State Licensed, Hearing Instrument Specialist. For over 9 years I have provided quality health care services to thousands of our state's hearing impaired. Presently, all three members of the hearing health care delivery team, (Hearing Instrument specialists, Audiologists, and Physicians) are recognized as qualified entry points into the hearing health care delivery system. The rule FDA is advocating would allow audiologists without any justification, to instill themselves as the sole entry point into hearing healthcare by allowing states to require expensive and non essential tests that only audiologists are qualified to perform.

Allowing audiologists an exclusive role in the hearing aid delivery system, without unqualified medical data evidencing that such a role is necessary for public health reasons, would severely undermine public health and safety and would increase costs to the hearing impaired.

The medical community, specifically the American Academy of Otolaryngologist (Ear, Nose and Throat) OPPOSES this FDA proposal

Please urge that this FDA proposed hearing aid rule be withdrawn.

I look forward to your response.

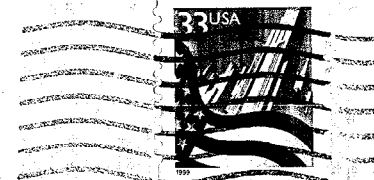
Cordially,

*Jim Kol Pak*

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Yun Kol Pak  
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